Unlocking New Treatment Options for Patients with Ovarian Cancer

FOUNDATION MEDICINE®

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommend Molecular Testing in Ovarian Cancer[1]

1 For patients with pathologically confirmed ovarian cancer,

a. Recommend genetic risk evaluation and germline and somatic testing (if not previously done). **Germline and/or somatic *BRCA1/2*** mutation status informs maintenance therapy after first-line platinum-based chemotherapy.

b. In the absence of a *BRCA1/2* mutation, **homologous recombination deficiency (HRD) status** may provide information on the magnitude of benefit of PARP inhibitor as maintenance therapy after first-line platinum-based chemotherapy (category 2B).

2 For patients with persistent or recurrent ovarian cancer,

a. Recommend tumor molecular testing, using the most recent available tumor tissue, including at least ***BRCA1/2* and microsatellite instability (MSI) or DNA mismatch repair** if not previously done.

b. **Evaluation of HRD** can be considered.

c. **Additional somatic tumor testing can be considered** at the physician's discretion to identify genetic alterations for which FDA-approved tumor-specific or tumor-agnostic targeted therapy options exist.

Our portfolio of tests analyzes guideline recommended genes for relevant alterations in patients with ovarian cancer including *BRCA1/2* somatic and germline*, other homologous recombination repair (HRR) pathway gene alterations resulting in HRD, and MSI.

*Foundation Medicine detects both somatic and germline alterations but does not differentiate between the two on reports.

Advancing Therapy Options for Ovarian Cancer Patients

FDA-Approved therapies, including the **bolded therapies** for which FoundationOne®CDx is the companion diagnostic

BIOMARKER	FDA-APPROVED THERAPY
BRCA1/2	**Lynparza®** (olaparib) **Rubraca®** (rucaparib) Zejula® (niraparib)*
gLOH	Rubraca® (rucaparib)
MSI-H	Keytruda® (pembrolizumab)
NTRK fusions	Rozlytrek® (entrectinib) Vitrakvi® (larotrectinib)

**BRCA1/2* mutation not required for use as a monotherapy in the first-line maintenance setting

Value of Comprehensive Genomic Profiling with Foundation Medicine

Our portfolio of tests detects additional biomarkers in genes known to be relevant in ovarian cancer, including genomic Loss of Heterozygosity (gLOH) which is associated with improved progression free survival (PFS) from Rubraca® (rucaparib) maintenance therapy in accordance with the Rubraca® product label as found in the ARIEL2 study using Foundation Medicine's NGS assays.[2]

When using Foundation Medicine tests, 19.5% of ovarian cancer patients were identified as having HRR alterations.[3]

Our portfolio of tests analyzes known and emerging HRR pathway genes, including *ATM, ATRX*, BAP1*, BARD1*, BRCA1/2, BRIP1*, CHEK1*, CHEK2, FANCA*, FANCL*, MRE11A*, NBN**, PALB2, RAD51*, RAD51B**, RAD51C**, RAD51D**, RAD52**, and RAD54L***[4]

*Not included on FoundationOne Liquid **Only included on FoundationOne CDx

Growing Therapy Options in Ovarian Cancer

Genomic alterations and biomarkers relevant for clinical trials or with novel therapies

MOLECULAR ALTERATION	→ DRUG CLASS
FGFR	*FGFR* Inhibitors
ARID1A	*EZH2* Inhibitors
CCNE1	*CHK1* Inhibitors
FOXL2[5]	Endocrine-based
TSC2, PIK3CA, AKT2, etc.[6]	*PI3K/AKT1/MTOR* pathway inhibitors
BRCA1/2	*PARP* inhibitors

A portfolio of tests to help identify more treatment options:

FOUNDATIONONE®CDx

TISSUE BIOPSY

FoundationOne CDx is FDA-approved with Medicare coverage for qualifying Medicare patients.[7]

- Analyzes 324 genes
- Reports gLOH*, TMB and MSI
  *in ovarian tumor tissue only

FOUNDATIONONE®LIQUID

LIQUID BIOPSY

FoundationOne Liquid is a laboratory developed test that delivers high-quality answers from a simple blood draw.

- Analyzes 70 genes
- Reports MSI-H status

TO LEARN MORE:

Visit *www.foundationmedicine.com*

TO SIGN UP OR ORDER A TEST:

Visit *www.foundationmedicine.com/signup*

FoundationOne®CDx is the only FDA-approved in vitro diagnostic test by Foundation Medicine. FoundationOne Liquid and FoundationOne Heme were developed and their performance characteristics determined by Foundation Medicine. They have not been cleared or approved by the U.S. Food and Drug Administration. For more information on our laboratory developed tests please see Technical Specifications at www.foundationmedicine.com.

FoundationOne®CDx is a next-generation sequencing based in vitro test intended for use by healthcare professionals for advanced cancer patients with solid tumors. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is FDA-approved as a companion diagnostic to identify patients who may benefit from treatment with a specific list of therapies (listed in Table 1 in the Technical Information at http://www.foundationmedicine.com/f1cdx) in accordance with the approved therapeutic product labeling. Additional genomic findings, other than those listed in Table 1, may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment or clinical trial option, or that all relevant alterations will be detected. Some patients may require a biopsy. For the complete label, including important risk information, please visit http://www.foundationmedicine.com/f1cdx.

References:

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer V.1.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed March 25, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
2. Swisher, E. M. et al. (2017) Rucaparib in relapsed, platinum-sensitive high-grade ovarian carcinoma (ARIEL2 Part 1): an international, multicentre, open-lable, phase 2 trial. Lancet Oncology, 18(1), pp. 75-87.
3. Internal data on file.
4. Chung JH, et al. JCO Precis Onco. 2019; 3:10.1200
5. Georges, A., Auguste, A., Bessière, L., Vanet, A., Todeschini, A., & Veitia, R. (2014). FOXL2: a central transcription factor of the ovary, Journal of Molecular Endocrinology, 52(1), R17-R33.
6. Cheaib, B., Auguste, A. and Leary, A. (2015), The PI3K/Akt/mTOR pathway in ovarian cancer: therapeutic opportunities and challenges. Cancer Communications, 34: 4-16.
7. Medicare and Medicare Advantage members have coverage of FoundationOne CDx in accordance with the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD) criteria.

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